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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01 D-02691

Draft Guidance for Industry on the Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until November 26, 2001, the comment period for the draft guidance for industry entitled "Clinical Studies Section of Labeling for Prescription Drugs and Biologics-Content and Format" that appeared in the **Federal Register** of July 9, 2001 (66 FR 35797). This draft guidance is part of a comprehensive effort to improve the format and content of prescription drug labeling. The agency is taking this action in response to a request for an extension and to allow interested parties additional time to submit comments.

DATES: Submit written or electronic comments on the draft guidance by November 26, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827-3844, FAX 1–888–CBERFAX, or Voice Information System at 800-835-4709 or 301-827-1800. Send one self-addressed, adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305),

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Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the-draft guidance document.

FOR FURTHER INFORMATION CONTACT: Janet M. Jones, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758, or Toni Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or e-mail: stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In **the Federal Register** of July 9, 2001 (66 FR 35797), FDA announced the availability of a draft guidance for industry entitled "Clinical Studies Section of Labeling for Prescription Drugs and Biologics-Content and Format." As part of a comprehensive effort to make prescription drugs safer to use, FDA is engaged in several initiatives to make prescription drug labeling a better information source for health care practitioners-clearer, more informative, more accessible, and more consistent from drug to drug. Recently the agency published a proposed rule to revise the overall format of prescription drug labeling (65 FR 81082, December 22, 2000). The agency also is developing a number of guidance documents that focus on the content of certain labeling sections. The first draft guidance entitled "Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics" was made available for public comment on June 21, 2000 (65 FR 38563).

The draft guidance entitled "Clinical Studies Section of Labeling for Prescription Drugs and Biologics-Content and Format" is the second guidance document on the content and format of individual labeling sections. Among other things, the draft guidance discusses what studies to include in the Clinical Studies section, how to describe those studies, and how to present clinical study data in graphs and tables. The agency also is trying to raise awareness, with this draft

guidance, of the implications for product promotion of information contained in the Clinical Studies section. This section exists in the current labeling and is expected to continue to exist when the proposed rule to revise the format for prescription drug labeling is made final.

On October 1, 2001, FDA received a request from the Pharmaceutical Research and Manufacturers of America (PhRMA) to extend the comment period. PhRMA indicated that it needed additional time to coordinate comments from its member-companies. In response to this request, and to provide all interested persons additional time to comment on this draft guidance, FDA is reopening the comment period until November 26, 2001.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday;

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm, or at http://www.fda.gov/cber/guidelines.htm.

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November 14, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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